Veterinary Medicines Directorate

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Post Authorisation Assessments

Tolfedine 4% Solution for Injection for Use in Dogs and Cats

Vm 08007/4048

October 2025	Introduction of a manufacturer of the active substance supported by an ASMF.
13 October 2023	Change of the address of the MAH holder from Vétoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northamptonshire, NN12 7LS, United Kingdom.
26 April 2023	Change in specifications of an excipient to comply to the Ph. Eur.
04 March 2022	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
30 March 2015	Change in name of the active substance manufacturer.
15 August 2014	Deletion of a secondary packaging site.
02 June 2010	Corrections to the wording on section 4.5 of the SPC.
21 January 2010	Harmonisation of the SPC.
04 April 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
18 March 2008	Renewal.
12 February 2008	Change in the name and address of the manufacturer of the active substance.
28 December 2007	Change in a primary packaging component: flip off caps.
12 November 2004	Renewal.
24 August 2004	Variation concerning the secondary assembler of the dosage form.
18 August 2004	Change of address of the Marketing Authorisation Holder.
24 January 2003	Addition of an Indiciation.
14 February 2000	Renewal.
19 June 1996	Change of company name.